UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN, the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK *ex rel.* STEVEN M. CAMBURN,

Plaintiffs,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

No. 13 Civ. 3700 (RA)

NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS RELATOR'S AMENDED COMPLAINT

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PRELIMINARY STATEMENT

The amended *qui tam* complaint in this case alleges that beginning in "2010 or 2011" and continuing to date, Novartis Pharmaceuticals Corporation ("Novartis" or the "Company") conducted speaker programs for its multiple sclerosis drug, Gilenya, resulting in violations of the Anti-Kickback Statute and False Claims Act. The amended complaint ("Amended Complaint") purports to plead a "pervasive kickback scheme" that was "widespread and orchestrated from the highest levels of the Company", and that "resulted in requests for payment by" various government healthcare programs for Gilenya. Amended Complaint, Dkt. No. 27 ("AC") ¶¶ 2-3, 14, 92. These allegations, however, fall far short of adequately stating any coherent theory of liability.

As an initial matter, Relator fails to allege with adequate particularity how the speaker programs were used as kickbacks to reward or induce prescriptions of Gilenya. He variously characterizes Novartis's speaker programs as "excessive", "lavish", and "shams", but does not allege (let alone support with specific facts), for example, that doctors who served as speakers received fees in excess of fair market value for the services they provided, or that the speaker programs had no educational value. Instead, Relator alleges that his supervisor encouraged him and his fellow sales representatives in the eastern Pennsylvania territory where they worked to organize what he viewed as an "excessive" and "shocking number" of speaker programs. AC ¶¶ 107, 109-10. But even then, he does not explain how or by what metric the number of events was "excessive". Likewise, while he characterizes the meals at certain speaker events as "excessive" and "lavish", *e.g. id.* ¶¶ 101-02, the facts Relator actually alleges are only that the expense of a handful of programs exceeded limits set by internal Novartis policies. Relator also alleges that Novartis would on occasion pay speakers when events were canceled due to lack of confirmed attendees, but he fails to allege facts suggesting that this practice

(which, according to Relator, a Novartis supervisor actually instructed should be avoided) was part of a scheme to pay kickbacks. In sum, Relator does not identify how the alleged deployment of unnecessary, "lavish", or canceled speaker programs rendered them kickbacks, and which of the Gilenya speaker programs or payments were rendered kickbacks on these theories.

Having failed to identify the speaker programs that constituted kickbacks, or to whom the kickbacks were supposedly given, it is unsurprising that Relator does not identify which claims were submitted to the government as a result of a kickback. While the Amended Complaint attaches a list of 100 doctors who allegedly received Novartis speaker payments and submitted claims to Medicare in 2013 and 2014, Relator does not even attempt to link the vast majority of these doctors to the alleged scheme at all. Of the twelve doctors that are named in the Amended Complaint, Relator's allegations fall far short of pleading that they participated in "sham" events or otherwise received kickbacks, and thus there is no basis for the Amended Complaint's assumption that the claims they submitted were false. The Amended Complaint alleges no facts with respect to any remaining doctors, other than that they received payments in connection with speaker programs and that their patients received Medicare reimbursements. Relator fails to allege any facts at all about the circumstances of the speaker payments these doctors allegedly received, let alone facts suggesting that the speaker payments were illegitimate.

Finally, Relator fails to plead in a nonconclusory way that Novartis, as a company, had knowledge of the supposed kickback scheme, which is fatal to his claims as corporate scienter is a prerequisite to a finding of corporate fraud. The Amended Complaint contains no allegations suggesting that the Company's policies encouraged the alleged kickbacks—in fact, it suggests the opposite—and contains no allegations of conduct or

statements of Novartis senior management that would suggest the company knowingly conducted the alleged scheme. In short, the Amended Complaint fails to allege violations of the Anti-Kickback Statute and the False Claims Act (and their state law analogues) since the kickback scheme and resulting claims are not adequately identified, and Relator fails to plead the required element of scienter with particularity. Accordingly, the Amended Complaint must be dismissed.

BACKGROUND

Relator, Steven M. Camburn, was employed by Novartis from 2010 until July 2013. AC (Dkt. No. 27) ¶¶ 8-9. He filed the original complaint in this case under seal on May 31, 2013. Dkt. No. 16. After a four-year investigation, the U.S. Attorney's Office for the Southern District of New York notified this Court that it would not intervene. Dkt. No. 15. After Novartis moved to dismiss the original complaint, Dkt. No. 25, Relator filed the Amended Complaint on September 10, 2018. Dkt. No. 27.

The Amended Complaint relates to doctor speaker programs and patient education events for the Novartis drug Gilenya. Gilenya is prescribed for the treatment of patients with relapsing forms of multiple sclerosis ("MS") to "delay the accumulation of [the] physical disability" characteristic of chronic MS. AC ¶ 90. In 2010, Gilenya became "the first oral disease modifying therapy . . . to treat the chief form of MS", which affects "approximately 80% of MS patients". *Id.* ¶ 88. The Amended Complaint alleges that there are "several similarly efficacious MS drugs in the marketplace with better safety and tolerability than Gilenya", *id.* ¶ 90—thus making marketing and outreach to educate healthcare providers and patients about Gilenya's risks and benefits and to dispel any misperceptions highly important.

Speaker programs are used as a promotional tool by pharmaceutical companies in order to educate healthcare providers and patients about medication and patient treatment options. A peer-to-peer event is a program for healthcare providers in which a speaker, hired by a pharmaceutical company, presents information about the drug to other healthcare practitioners. *Id.* ¶ 106. In contrast, patient events involve healthcare providers presenting information about the drug to an audience of current and prospective patients. *Id.* The presentations at patient events are different from peer-to-peer events because they are geared toward patients rather than healthcare professionals.

The Amended Complaint alleges that starting in "2010 or 2011", *id.* ¶ 14, Novartis paid kickbacks to physicians by hiring them to speak at peer-to-peer and patient events intended to induce them to write more prescriptions for Gilenya, *id.* ¶ 1. Relator alleges that by paying kickbacks to healthcare providers, Novartis caused the submission of false claims for payment to Medicare, Medicaid, TRICARE, Veterans Administration Health Care and possibly other federally funded government healthcare programs. *Id.* ¶ 3. The Amended Complaint alleges that this scheme continues "to date", *id.* ¶ 14, but contains no actual allegations concerning any events taking place after 2013.

The Amended Complaint centers around the activities of Vince Schaeffer, a Novartis employee who worked in the eastern Pennsylvania region beginning in 2012, and with whom Relator worked personally. *Id.* ¶ 106. Relator alleges that Mr. Schaeffer demanded that the region run a significant number of patient and peer-to-peer events without regard to the quality of the programs. *Id.* ¶¶ 110, 113. Specifically, Mr. Schaeffer allegedly required his sales team to schedule 16 patient events and eight peer-to-peer events per trimester in each of the Pennsylvania territories he oversaw, *id.* ¶ 106, and considered the number of patient events that

sales representatives scheduled in their performance reviews, *id.* ¶ 109. The Amended Complaint also alleges that on one occasion, some members of the sales team raised concerns about the value of patient events to then Vice President and Head of Sales Randi Roberts, and that she listened to the concerns that were raised but did not recommend any changes to the patient events—allegedly congratulating the group for doing the most events in the Company. *Id.* ¶ 115.

The Amended Complaint makes limited factual allegations about the events themselves. With respect to the peer-to-peer events, it alleges that they were "normally an expensive dinner or meal", *id.* ¶ 106, and that out-of-town speakers often requested and were given multiple speaking engagements during one trip, *id*. ¶ 123. The Amended Complaint alleges that patient events were "normally a desirable dinner", *id.* ¶ 106, that some patient events had low attendance, that patients' family members would sometimes attend, and that some patients would attend events on more than one occasion, *id*. ¶ 114.

The Amended Complaint asserts that Mr. Schaeffer made certain statements during the relevant period suggesting an improper motive in scheduling the events, including: that the value of patient events was "taking care of the speaker", *id.* ¶ 113; that when patient events were declining in 2013, the Company needed to find new ways to show a particular doctor "love and keep him happy", *id.* ¶ 118; and that the sales force needed to ask doctors "to return the favor and submit more prescriptions" when the rate of new prescriptions was slowing, *id.* ¶ 121. The Amended Complaint alleges that Mr. Schaeffer "had little to no interest" in using a particular registered nurse as a speaker "because of his belief that there would be a minimum return on investment", given her inability to write prescriptions. *Id.* ¶ 120. Relatedly, the Amended Complaint alleges that four doctors who were approved speakers accounted for 43% of

the Gilenya prescriptions in the Philadelphia territories, *id*. ¶ 111, and that the nurse who served as an approved speaker was given fewer speaking engagements than doctors with prescription-writing privileges, *id.* ¶ 112.

The original complaint described only one specific speaker event, and this description is repeated in the Amended Complaint. On August 22, 2012, "Dr. M.K.", an out-of-town speaker, is alleged to have spoken at a program at a restaurant in Philadelphia. *Id.* ¶ 123. The attendees were "doctors, nurses, medical students and medical assistants", and an additional six attendees from Novartis, including Relator. *Id.* There is no allegation that the event was illegitimate or lacking in educational value, and there is no allegation about Dr. M.K.'s prescription writing for Gilenya. Instead, the Amended Complaint alleges only that the bill exceeded the $125-per-person limit established by the Company's internal policy, *id.*, and that the account manager "seemed rattled" by the bill and added two names to the attendance list to reduce the per-person cost, *id.* ¶ 124.

The Amended Complaint also alleges that sales representatives were responsible for ensuring that speakers were "on message", which Relator interprets to mean they were experienced with Gilenya, had a favorable outlook on Gilenya and had the ability to speak to peers convincingly about its merits. *Id.* ¶ 133. It alleges that "Novartis speakers were often paid to speak repeatedly to the same offices or even to other physicians within their own practice", *id.*, and that management would track speakers' prescriptions and consider "using a different speaker or reducing a speaker's commitments" when prescriptions decreased, *id.* The Amended Complaint does not describe any speaking engagements that would support these allegations, or any instance in which speakers' engagements or payments were altered based on their prescription writing.

Novartis moved to dismiss the original complaint on August 20, 2018, arguing, first, that it (1) failed to plead the existence of a kickback scheme with particularity, as it lacked non-conclusory allegations concerning how the alleged kickback scheme worked and details concerning specific events that were used to pay kickbacks to speakers; (2) failed to plead any specific false claims connected to the alleged kickback scheme; and (3) failed to plead facts supporting the requisite inference that Novartis acted with scienter, as it failed to link its allegations concerning Mr. Schaeffer to any broader company policy or knowledge on the part of more senior officials within the company. Dkt. No. 25.

In the face of these arguments, Relator amended his complaint to add, principally, the following allegations:

- that a Novartis Vice President, Dagmar Rosa-Bjorkeson, made statements concerning Gilenya's sales through 2012, and praised the Company's MS business unit for "exceptional performance", AC ¶ 91;
- that Novartis provided speakers with slide decks to present at speaker programs that were "rudimentary, overly simplistic, and repetitive" because they repeated information that is on the drug package's label insert, AC ¶ 96;
- that, in Relator's experience, the presentation of the slide decks at speaker programs usually lasted "at most 20 minutes" and often did not cover the entire deck, AC ¶ 96;
- that Novartis's cancellation policy (allowing speakers to be paid if the events were canceled less than 48 hours beforehand) led speakers to be paid even when events did not occur, and this was a "tactic" to "make illegal payments to doctors", AC ¶ 99;

- that Novartis used "lavish" meals to attract attendees to speaker programs and that sales personnel would take steps to "circumvent[]" the $125-per-person limit, AC ¶ 102; and
- that, in addition to the event involving Dr. M.K. described above, there were other similar events, including four identified events, some of which took place at "high-end" restaurants, exceeded Novartis's $125 "meal spend limit", and were expensed using documentation that was "altered" to appear compliant with Novartis policy, *id.* ¶¶ 101-104.

In addition, in response to Novartis's argument that the original complaint failed to plead any specific false claims connected to the alleged kickback scheme, Relator appended Exhibit A to the Amended Complaint, which purports to show a list of some portion of Novartis's paid speakers (by initials); the speaker payments those doctors allegedly received from Novartis between 2013 and 2014; the Medicare reimbursements for prescriptions written by those doctors in 2013 and 2014; and the total number of Medicare claims each doctor allegedly submitted in those years. *Id.* ¶¶ 125, 130, 136, Ex. A. The Amended Complaint insinuates that *all* of the Medicare claims summarized in Exhibit A were "tainted by Novartis's paid-speaker scheme", *id.* ¶ 136, but it does not allege facts on which that inference can be drawn.

Based on the above, the Amended Complaint alleges that Novartis violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, and state law analogues.

ARGUMENT

Claims brought under the FCA are governed by the heightened pleading standard set forth in Rule 9(b) of the Federal Rules of Civil Procedure, *see Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995), which requires that both the fraudulent scheme and the

submission of false claims be pled with a high degree of particularity. *See, e.g.*, *United States ex rel. Arnstein v. Teva Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 WL 750720, at *13 (S.D.N.Y. Feb. 22, 2016).[1] To satisfy the Rule 9(b) pleading requirement and survive a motion to dismiss under Rule 12(b)(6), the complaint must identify the "who, what, when, where and how of the alleged fraud". *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009). In addition, the relator must "allege the particulars of the false claims themselves". *United States ex rel. Corp. Compliance Assocs. v. New York Soc. for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 Civ. 292(PKC), 2014 WL 3905742, at *11 (S.D.N.Y. Aug. 7, 2014). Finally, the relator must allege facts that give rise to a "strong inference" that the defendant acted with actual knowledge, deliberate ignorance or reckless disregard of the conduct at issue. *See, e.g.*, *Teva*, 2016 WL 750720, at *28.

The Amended Complaint fails to satisfy these pleading requirements. It does not allege a fraudulent kickback scheme with particularity (*see* Part I, *infra*), does not allege false claims for payment made to any government program resulting from the alleged kickback scheme (*see* Part II, *infra*), and does not allege that the Company had any fraudulent intent with regard to Gilenya speaker programs (*see* Part III, *infra*).

[1] Rule 9(b) applies equally to the state law analogues identified in the Amended Complaint. *See, e.g.*, *Teva*, 2016 WL 750720, at *11 ("Rule 9(b) applies to claims brought under the FCA and its state law analogues."); *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (Rule 9(b) "applies to *qui tam* actions under state statutes similar to the FCA").

I. The Amended Complaint Fails To Plead the Existence of a Kickback Scheme with Particularity

When an FCA claim is premised on alleged violations of the Anti-Kickback Statute, the complaint must plead with particularity "the who, what, when, where and how" of the underlying kickback scheme. *Polansky*, 2009 WL 1456582, at *4. The burden is on the relator to identify which programs were fraudulent. *See, e.g.*, *United States ex rel. Smith v. New York Presbyterian Hosp.*, No. 06 Civ. 4056(NRB), 2007 WL 2142312, at *5-7 (S.D.N.Y. July 18, 2007) ("Without a description of any actual fraudulent billing, Defendant is forced to search its records for evidence to prove it did not commit fraud, releasing [relator] from the burden of proving that fraud was actually committed."). Where specific details about the underlying kickbacks are absent, the complaint must be dismissed. *See id.* at *6 n.43 (dismissing complaint that "summarily assert[ed] . . . that defendants billed for studies that were never taken, but fail[ed] to provide an example of, or any details about, any such bill"); *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045, 1049 (N.D. Ill. 2002) (dismissing complaint that alleged that hospital's purchases of medical practices constituted kickbacks but failed to "identify what assets were purchased, the amounts paid, or anything beyond conclusory allegations that they were not commercially reasonable").

The Amended Complaint alleges that Novartis's peer-to-peer and patient events were part of a "pervasive kickback scheme whereby Novartis paid remuneration to physicians . . . to induce them to write and to continue writing prescriptions" for Gilenya. AC ¶ 92. However, it fails to provide sufficient elaboration as to *how* the events were illegitimate, which is a necessary predicate to finding that they served as kickbacks to the doctors who spoke at them. Although the Amended Complaint makes various allegations about "tactics" used to

pay kickbacks to speakers, it fails to provide particularized support, let alone any coherent theory of how the alleged scheme was carried out.

First, the Amended Complaint alleges that sales representatives paid doctors for speaker events that did not take place and intentionally canceled events within 48 hours so that the speaker would be paid despite low anticipated attendance. AC ¶¶ 98-99. However, it does not allege facts about a single instance in which this actually occurred, instead simply identifying three doctors who allegedly received payments for unspecified canceled events from 2012 to 2013. *Id.* ¶ 99. The Amended Complaint does not even allege that the canceled events for which Novartis speakers received payments related to Gilenya. *Id.*

Second, the Amended Complaint alleges that the number of speaker programs Novartis conducted was "excessive", based largely on the allegation that Mr. Schaeffer set high goals for speaker programs in each of his three territories. This is merely an allegation that Relator and his team organized more events than Relator thought were necessary, without explanation of how the "excessive" events were improper or constituted kickbacks.[2] And by simply alleging that the speaker programs in Relator's region and elsewhere were improper because there were too many of them provides Novartis with no ability to discern *which* of the

[2] In fact, Relator alleges no facts and provides no adequate explanation to support his assertion that the number of speaker programs was excessive. With respect to patient events, Relator seems to infer this conclusion from his allegation that there was low and repeat attendance among patients, and that patients sometimes attended with their families. AC ¶¶ 65-66. There are, of course, legal restrictions, including rules promulgated pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"), on what Novartis can do to contact patients or to track their attendance, *see, e.g.*, 45 C.F.R. §§ 160, 164, so the fact that some events had repeat attendees or an insufficient number of attendees would have been outside Novartis's control. Fundamentally, and consistent with his failure to explain how the kickback scheme worked, Relator does not explain how patient attendance at these events has any bearing on the ultimate question of whether the events served as kickbacks *to doctors*.

Gilenya speaker programs were improper—or, in turn, which claims arising from those events were false.

Third, the Amended Complaint alleges that sales representatives hosted events that were "lavish" and "exceed[ed] the meal spend" allowed for under Novartis policy, *id.* ¶¶ 101-104, but that internal policy violation cannot be the basis for inferring a kickback. One such program the Amended Complaint identifies was a peer-to-peer event with an out-of-town speaker, Dr. M.K. *Id.* ¶¶ 103, 123-124. The only factual allegation about payments made to Dr. M.K. is that "he requested and was given three speaking events for his trip", implying that he was paid for three presentations. *Id.* But there is no claim that he did not provide services for the fees that he was paid, or that he was paid more than fair market value for his time and services. *Id.* ¶¶ 123-124;[3] *see United States ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc.*, No. 05 Civ. 5393(RPP), 2011 WL 1330542, at *2 (S.D.N.Y. Apr. 5, 2011), *aff'd sub nom., United States v. Quest Diagnostics Inc.*, 734 F.3d 154 (2d Cir. 2013) (explaining that "the AKS defines 'remuneration' as including 'transfers of items or services for free or for other than fair market value'").

The same is true of the other four speaker programs Relator identifies, which are newly alleged in the Amended Complaint but add nothing to the legal analysis. These events each allegedly exceeded the Company's $125-per-person limit for *attendees* at the peer-to-peer programs. *Id.* ¶ 104. Such allegations have nothing to do with the issue of whether the events themselves were used as a vehicle for paying a kickback to the *speaker*. At most, what the

[3] It is, of course, unremarkable that a physician traveling from out of town would be given "multiple speaking engagements", *id.* ¶ 84, as it is a more efficient use of the speaker's time and more valuable to the Company to take advantage of his visit to the region.

Amended Complaint shows is that on five occasions between August 2012 and June 2013, at different venues in different parts of the country, a sales representative hosted a speaker program that went over budget. If it were the case that sales representatives attempted to alter event documentation on these particular occasions to make them appear compliant, as Relator alleges, that supports a conclusion that Novartis *lacked* the requisite scienter (*see infra* Part III), as it would only reinforce the point that Novartis had a policy in place limiting the budget for speaker programs, and that these sales representatives were concerned about the potential consequences of noncompliance. While the Amended Complaint identifies the doctors that spoke at these events, it makes no allegations suggesting these events were inducements or rewards for those doctors' prescription writing.[4]

With respect to these speakers and other unnamed doctors, the Amended Complaint alleges that Novartis "evaluated the number of speaking engagements they should be given on the basis of the number of prescriptions of Gilenya written", *id.* ¶ 119, but provides no specific facts concerning this allegation, and does not allege that speakers were actually given more or fewer speaking engagements on the basis of their prescription volume. Relator attempts to suggest that speaker fees were meant to reward speakers in the Philadelphia territories for prescribing Gilenya by stating: "It is no coincidence that in 2012, the four prescribing speakers paid to conduct Patient Events account for 43 percent of Gilenya prescriptions written for that region." *Id.* ¶ 63. However, this is a particularly weak inference given how recently Gilenya had

[4] The Amended Complaint merely alleges, in a conclusory manner, that the "lavish" dinners were used "as the hook to get attendees to the program", *id.* ¶ 102, while only alleging a handful of examples where this supposedly occurred. As with the Amended Complaint's allegations about attendees at patient events, *see supra* at 11 n.2, this allegation about attracting attendees to peer-to-peer events has nothing to do with whether the events constituted kickbacks to *speakers*.

entered the market, and the need to have speakers with significant clinical experience with the drug give presentations at peer-to-peer and patient events. Moreover, this is a far cry from the allegations in other cases where the complaints actually identified specific doctors whose speaker fees increased as their prescription numbers grew, *see, e.g.*, *Teva*, 2016 WL 750720, at *5, or doctors who were removed from the company's list of approved speakers because of their failure to write more prescriptions, *id.* at *3.

Finally, Relator does not plausibly allege that the events lacked educational value, either for the doctors who attended peer-to-peer events or the patients who attended patient events. In another *qui tam* case brought in this district, the court found that the complaint pled a "[p]lausible [k]ickback [s]cheme" because, among other things, it alleged that "the speaker programs—while educational in some abstract sense—were not educational for anyone providing or attending the programs, in that they offered no new content, and were given to the same attendees repeatedly—even sometimes given to no one at all outside of [the company] itself." *Teva*, 2016 WL 750720, at *16. Other speaker program cases that have survived motions to dismiss have alleged with particularity that events "were given at unconventional venues or in the absence of bona fide attendees", *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1055 (C.D. Cal. 2016), and other FCA cases have alleged that healthcare providers were given more than fair market value for their time and services, *Quest Diagnostics*, 2011 WL 1330542, at *2.

Here, by contrast, Relator makes no particularized allegation that the events were given at unconventional venues, in the absence of bona fide attendees or that speakers were paid more than fair market value for their time and services. In fact, as to the events the Amended Complaint does describe, they took place in conventional restaurant venues, AC ¶¶ 103-104, and

there were doctors, nurses, medical students and other healthcare practitioners in attendance, *id.* ¶ 123. In an attempt to cure this failing, the Amended Complaint includes a new allegation that the content of Novartis's slide decks for speaker programs "repeat[ed] the drug package label insert information" and the information that sales representatives provided to doctors during office visits, *id.* ¶ 96, and was not always covered in its entirety during a speaker's presentation,[5] *id.* That the information presented in the slide decks would be consistent with the drug package label and the communications of sales representatives is to be expected, because of FDA regulations that require promotional materials, including slide decks used at company-sponsored speaker programs, to include "[a]dequate information" for the use of the drug, using language that is the same as or consistent with labeling language approved by the FDA. 21 C.F.R. §§ 201.100(d)(1), 202.1(l)(2). And, unlike in *Teva*, there is no allegation here that slide decks were not presented at all, that decks were superficially altered to "disguise" repetition or that events were held with only Novartis employees in attendance. *Teva*, 2016 WL 750720, at *4.

* * *

In sum, the Amended Complaint should be dismissed because it fails to plead the particulars of how the alleged kickback scheme worked and fails to identify instances in which an alleged kickback was paid.

[5] The only support for this last assertion is Relator's alleged personal experience hosting and attending speaker programs in eastern Pennsylvania, at which he claims speakers presented the entire slide deck at 10% of the peer-to-peer events and 20-30% of the patient events. *Id.* ¶ 96. Despite claiming to have observed this personally, he does not provide a single example of an event where this occurred. Moreover, that Relator allegedly observed this in one small region does not mean it was the case across the Company, and more importantly, does not mean the events constituted kickbacks.

II. The Amended Complaint Fails To Identify Specific False Claims Connected to the Alleged Kickback Scheme

The Amended Complaint must also be dismissed because it fails to allege with specificity any false claims connected to the alleged kickback scheme. Under the FCA, liability attaches "not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment'". *Polansky*, 2009 WL 1456582 at *5 (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)); *see also United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 256 (S.D.N.Y. 2014) ("[R]equiring a plaintiff to provide enough detail for a defendant to be able to reasonably identify particular claims that are allegedly false better fulfills the central purpose of Rule 9(b)—providing fair notice to the defendant."). Even if the Amended Complaint pled with particularity the existence of a kickback scheme, it nonetheless fails because it does not identify false claims submitted to any federal healthcare programs as a result of the alleged kickbacks, as required under the FCA. *See Smith*, 2007 WL 2142312, at *6 ("Although [Relator] manages to sketch out the nature of [his] claim by generally stating the 'who, what, where, when and how' of his theory of fraud, he fails to provide sufficient detail about that theory or about any specific fraudulent claim.").

To satisfy the requirement of particularity, a relator must provide identifying information about false claims, which can include "dates of claims, contents of claims, identification numbers, reimbursement amounts, goods or services provided, and individuals involved in the billing". *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 821 (S.D.N.Y. 2017), *rev'd on other grounds*, No. 17-2191-cv, 2018 WL 3763731 (2d Cir. Aug. 9, 2018). "[C]ourts also note the usefulness of data such as the name of the patient who received the good or service, the name of the medical professional who provided the good or service, the date on which the good or service was delivered, the name of the employee who submitted the

claim, and the government entity that reimbursed the claim." *Teva*, 2016 WL 750720, at *14 (quoting *Kester*, 23 F. Supp. 3d at 258).

The relators in *Teva* alleged details concerning the false claims and specific facts that linked those claims to the kickback scheme. The complaint there contained several dozen examples of "sham" speaker events, providing the date, location, speaker, presentation topic, number of attendees, amount of remuneration and other details about each one, along with a description of the basis for alleging the event was a kickback. *United States ex rel. Arnstein v. Teva Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM) (S.D.N.Y.), Dkt. No. 13 at ¶¶ 112-142. For example, the *Teva* relators identified specific events where there was no formal presentation given and no attendees from outside the company; events where the same small group of physicians took turns presenting on the same topic; and events that were repeated on multiple occasions with the exact same speaker, presentation and attendees. *Id.* And, crucially, for all speakers involved in these specific events, the relators made allegations as to their total number of claims for the drugs at issue. *Id.*

Here, in contrast, even though the Amended Complaint alleges that there were "thousands of false claims" for Gilenya, AC ¶ 135, it fails to plausibly allege any link between claims, the prescribers and the speaker programs. In an attempt to address the deficiencies of the original complaint, which failed to identify any false claims made by any Novartis-paid speaker, Relator now identifies three physicians who were allegedly paid for canceled programs and also submitted claims for Gilenya prescriptions in 2012-2013, *id.* ¶ 99, and encloses a list of

Novartis-paid speakers and their Medicare claims in 2013-2014, *id.*, Ex. A.[6] None of these allegations is sufficient to satisfy Relator's burden.

The allegation that three speakers received payments for canceled programs and also submitted claims for Gilenya prescriptions does not support an inference that the speaker payments were an inducement or reward for the speakers to prescribe Gilenya, nor does the Amended Complaint plead this. It merely alleges that "it is unsurprising" that speakers who received payments for canceled programs were also high Gilenya prescribers, without pleading any actual link between them. *Id.* ¶ 99. In fact, the Amended Complaint identifies one of these physicians, Dr. B.K., as the "founding member of one of the largest MS centers in the United States", *id.*, so it is entirely "unsurprising" that someone in his position would be a high prescriber of a medication used for MS treatment, whether or not he was involved in canceled events.

The list of alleged Novartis speakers and their Medicare claims during years 2013-2014 in Exhibit A similarly fails to satisfy Relator's burden to plead specific false claims. Although Relator describes Exhibit A as a "representative sample of false claims tainted by kickbacks for which reimbursement was obtained from the Medicare Part D program", *id.* ¶ 136, he alleges no facts to support this assertion. Relator does not make any allegations at all about the vast majority of the alleged speakers listed in Exhibit A. Out of 100 alleged speakers

[6] Relator also identifies two physicians who received patient marketing materials from Novartis and also submitted claims for Gilenya prescriptions in 2013-2014, *id.* ¶ 105. Relator "believes" that the purpose of these marketing services, which of course are unrelated to the speaker programs that are the subject of the Amended Complaint, was to increase the speakers' patient population in order to increase Gilenya prescriptions, but alleges no facts to support this assumption. And, even if true, this is not an example of a kickback that would render the claims for payment false.

included in the chart, the Amended Complaint only so much as mentions twelve of them, with limited discussion of each. AC ¶¶ 99, 103-105, 118, 121, 123-124.[7] The Amended Complaint contains no discussion of "sham" events at which they were speakers, or whether they were asked or agreed to write more Gilenya prescriptions because Novartis hired them to be Gilenya speakers. The Amended Complaint identifies these twelve doctors as being part of the alleged kickback scheme, but fails to identify a single kickback that was paid. Without knowing which were the supposedly improper speaker payments, Novartis cannot identify which were the resulting false claims; it is not enough for Relator to allege that a doctor received speaker payments during a two-year period and therefore all Medicare reimbursement claims during that same period must have been false.[8]

As it fails to sufficiently allege any link between Gilenya speaker payments and claims submitted to the government, the Amended Complaint fails to identify with particularity any allegedly false claims.

[7] For example, the Amended Complaint refers to Dr. L.H. and Dr. D.T., whom Mr. Schaeffer allegedly said should write more prescriptions because they were speakers. AC ¶ 118. The allegations about Mr. Schaeffer's statements in both cases are vague and do not show that the doctors were in fact paid kickbacks. The Amended Complaint alleges that Mr. Schaeffer stated, in response to slowing new prescriptions for these doctors, that his sales team should ask them "to return the favor and submit more prescriptions". *Id.* ¶ 81. It also alleges that Mr. Schaeffer stated that Dr. Harris was paid over $40,000 in speaking fees in 2012, as if to "insinuat[e] that he should be writing more Gilenya scripts in return". *Id.* Neither of these allegations describes any actual conduct on the part of Mr. Schaeffer, his sales team or the doctors who served as paid speakers.

[8] Exhibit A does not even clearly relate to payments for Gilenya speaker programs. A review of the column "Novartis Speaker Payments" for 2013 and 2014 suggests that some of these were not even speaker payments, as they were well under $1,500, the minimum amount alleged to have been a speaker fee. *Id.* ¶ 98. And there is no indication or allegation that these payments, even if made by Novartis, related to Gilenya.

III. The Amended Complaint Fails To Adequately Plead Scienter on the Part of Novartis

Even if the Amended Complaint did allege a coherent kickback scheme with sufficient particularity and identified at least a representative sample of specific false claims resulting from it—neither of which it does—the Amended Complaint still must be dismissed because it does not adequately plead scienter on the part of Novartis. A necessary element of the FCA is that the defendant acted "knowingly", which requires plausible allegations that the defendant had actual knowledge that false claims were submitted to the government, or acted in deliberate ignorance or reckless disregard of the truth or falsity of such claims. 31 U.S.C. § 3729(b)(1). Scienter is a "rigorous" element of the FCA that requires showing that "the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1996 (2016). To satisfy the pleading requirement of Rule 9(b), the Second Circuit "require[s] plaintiffs to plead [a] factual basis which gives rise to a strong inference of fraudulent intent". *United States ex rel. Tessler v. City of New York*, 712 F. App'x 27, 29 (2d Cir. 2017) (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)).

To support a "strong inference" that Novartis as a company acted with fraudulent intent, the Amended Complaint must link the sales representatives' conduct to the company's senior management. *See Teva*, 2016 WL 750720, at *5. In *Teva*, the complaint stated that the "pay-to-play scheme allegedly was the result of Teva management's express direction", that "Teva's corporate policy allegedly encouraged the kickback scheme", and that "managers throughout Teva allegedly encouraged sales representatives to use honoraria to incentivize physicians to write more prescriptions." *Id.* In fact, "[a]t the highest levels of management", Teva was alleged to have created a seminar for sales associates in which the "overarching

message to Teva's leadership team [*i.e.*, mid-level managers] was the more speaking opportunities you create to pay doctors, the more prescriptions they will write for Teva, and the more financial rewards you will receive". *Id.* (alteration in original).

No such allegations exist here about corporate policy or direction from senior management. The Amended Complaint fails to plead a factual basis supporting the inference that Novartis encouraged sales specialists to host sham events or that there was corporate intent on the part of Novartis to use Gilenya speaker programs for this purpose. The Amended Complaint alleges that a handful of speaker events did not comply with company policies and that some sales representatives attempted to cover up noncompliance, *see, e.g.*, AC ¶¶ 103-104, 122-124, but these allegations fall far short of demonstrating intent or direction from anywhere near the highest levels of the company. To the contrary, the fact that Novartis policy imposed a budget on speaker programs, *id.* ¶ 101, and at least after 2013 prohibited "canceled-paid programs" except under "unique circumstances", *id.* ¶ 100, shows that Novartis's policies aimed to *prevent* sales representatives from using speaker programs for the purpose of paying kickbacks to healthcare providers. There is no allegation that senior management directed or encouraged sales representatives to violate corporate policy, or that senior management had knowledge of or was deliberately indifferent about noncompliance—indeed, Novartis senior management is not mentioned at all. Nor is there any allegation that sales representatives would not be penalized for identified instances of noncompliance or misconduct. Accordingly, the Amended Complaint's allegations about the practices of some sales representatives do not "link the sales representatives' conduct to the company's senior management", *Teva*, 2016 WL 750720, at *5, which is fatal to Relator's claims.

Moreover, many of the Amended Complaint's allegations that purport to relate to corporate scienter are specific to a single regional manager, Vince Schaeffer. The allegation that Mr. Schaeffer documented the number of patient events that his sales representatives completed in performance reviews, AC ¶ 109, is insufficient to support an inference of scienter, as he was a manager in one segment of one state, and certainly not a member of senior management. Likewise, that Relator and other sales representatives expressed "concerns" about patient events on a few occasions similarly fails to support corporate scienter with regard to kickbacks. As to the complaints Relator claims that he had, and that members of his sales team expressed among themselves, related to the number of speaker programs Mr. Schaeffer asked them to organize, *id.*, and related to low or repeat attendance at some patient events, *id.* ¶¶ 114-15, these complaints did not allege the payment of kickbacks. And certainly such complaints do not raise any inference about the knowledge of Novartis senior management, as the Amended Complaint does not allege that the complaints rose to that level.

In fact, the highest-ranking Novartis employee to whom these concerns were allegedly escalated is Randi Roberts, who was Vice President in MS Sales. She is alleged to have attended a team meeting in Pennsylvania where concerns were raised and nonetheless "congratulated the group on doing the most events". *Id.* ¶ 115. However, the mere unsupported allegation that Ms. Roberts did not recommend changes to patient events in this small region in response to a single complaint does not establish that she intended for the patient events to be used to pay kickbacks, let alone that the Company's senior management—of which she was not a member—overlooked or failed to discipline issues of noncompliance as would be required to demonstrate scienter. The Amended Complaint names two additional Novartis employees in an attempt to remedy this defect, but the allegations concerning them do nothing to support an

inference of corporate scienter. The allegation that a Novartis Vice President and Head of the MS Business Unit, Dagmar Rosa-Bjorkeson, praised the unit for its efforts in promoting the growth of Gilenya and made factual statements about cumulative sales, *id.* ¶ 91, falls far short of an allegation that the Company knowingly caused the sales team to pay kickbacks to healthcare providers in order to fuel this growth. Similarly, the allegation that Ed McLaughlin, Sr. Area Business Leader for the MS unit, provided the sales team with direction on how to handle situations in which there were an insufficient number of attendees prior to an event, *id.* ¶ 100, does nothing to further Relator's argument. To the extent that Mr. McLaughlin's statement can be construed as a description of corporate policy, it demonstrates just the opposite of what Relator claims: that Novartis discouraged "canceled-paid programs".

There is no other executive or senior management-level employee identified in the Amended Complaint at all. And the only allegations as to the knowledge or intent of unnamed senior management are conclusory in nature. *See, e.g.*, *id.* ¶ 116 (alleging without support that the number of patient events in a handful of cities demonstrated a "corporate decision" to use the events as a vehicle for kickbacks); *id.* ¶ 117 (alleging that Mr. Schaeffer was "recognized nationally" for the amount of patient events his territory held in 2012); *id.* ¶ 98 (alleging that Novartis's payments to speakers were "disguised as 'honorarium'", even though such payments were, by definition, made in exchange for the speakers' services in promoting Gilenya). There are also allegations about purported company practices that are not attributed to any individuals or supported by any factual evidence or examples. *See id.* ¶ 119 (alleging without support that Novartis tracked prescriptions written by physicians and that "Novartis management" would intervene if a speaker was not writing enough prescriptions); *id.* ¶ 97 (alleging without support that Novartis does not conduct a "needs-assessment" for speaker

programs); *id.* ¶ 122 (alleging without support that Novartis would schedule peer-to-peer events with "verbal reservations" that would make them easier to cancel while still paying the speaker); *id.* ¶ 101 (alleging without support that a $125 per person budget for speaker program dinners was "facially excessive" in order to claim that they must have been intended as kickbacks). These unsupported statements about the Company's intent amount to nothing more than "sweeping and, so far as the complaint discloses, entirely unfounded assertion[s]". *United States ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 814 (S.D.N.Y. 2010).

In sum, the Amended Complaint seeks to draw an inference about corporate intent based largely on the activities of a single region, which the Amended Complaint alleges was "first in the nation" in conducting patient events and thus, even in Relator's view, not representative of company-wide practices. AC ¶ 116. In an attempt to broaden the geographical reach of the allegations, Relator now identifies a handful of sporadic events and speakers in other parts of the country, but still fails to connect the alleged conduct of some sales representatives to any corporate policy or direction from the company's senior management. In fact, while the Amended Complaint makes broad allegations that kickbacks were rampant and condoned "at the highest corporate levels" of the Company, *id.* ¶ 14, those allegations are entirely unsupported. The Amended Complaint fails to particularize its claim that Novartis intentionally encouraged, deliberately ignored or recklessly disregarded any fraudulent conduct, and therefore, Relator has failed to plead a factual basis that would demonstrate an inference of scienter as required under the FCA.

CONCLUSION

For the foregoing reasons, Relator's Amended Complaint should be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to plead fraud with particularity under Rule 9(b).[9] Because Relator has amended his Complaint once and has still failed to allege fraud with sufficient particularity, dismissal should be with prejudice.

Dated: September 24, 2018
New York, New York

Respectfully submitted,

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[9] Relator also alleges violations of false claims statutes of 30 different states and cities. All of these statutes are substantively similar to the FCA—indeed, many track the language of the FCA. AC ¶¶ 149-493. Therefore, for the same reasons discussed above, Relator's state law claims must also be dismissed. *See supra* at 9 n.1. Further, there is not a single false claim to a state government program identified, so there is no allegation that any of these states or cities made payments for false claims. Finally, because Relator fails adequately to allege violations of the AKS and FCA, Relator's allegation that Novartis's Best Price was inflated as a result of alleged kickbacks, AC ¶ 79, also fails.